의학석사 학위논문

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2014 년 08 월

서울대학교 대학원
의학과 영상의학 전공
황 인 평

A thesis of the Degree of Master of Science in Medicine

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August 2014

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이 논문을 의학석사 학위논문으로 제출함

2014 년 04 월

서울대학교 대학원

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2014 년 07 월

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ABSTRACT

Introduction: The aim of the present study was to investigate the feasibility and image quality of excretory CT urography (CTU) with low iodine concentration contrast media and low tube voltage.

Methods: This prospective study enrolled sixty-three patients who underwent CTU. The subjects were randomized into two arm of excretory phase CTU protocol; 480 seconds after intravenous injection of 1.5 mL/kg of ioversol with concentration of 240 mg I/mL (low-concentration protocol arm, n = 32) or 350 mg I/mL (conventional protocol arm, n = 31). Conventional protocol was performed with 120 kVp of tube voltage, in contrast, tube voltage was reduced to 80 kVp in low-concentration protocol. Two image sets with iterative reconstruction (IR) and filtered back projection (FBP) reconstruction were obtained in low-concentration group. Two readers were qualitatively evaluated images with 3-point scale for sharpness of urinary tract, image noise, streak artifact and 5-point scale for overall diagnostic acceptability. Mean attenuation, signal to noise ratio (SNR), contrast to noise ratio (CNR) and figure of merit (FOM = CNR^2 / effective dose) were measured at urinary tract. For statistical analysis, Wilcoxon signed-rank test was used between IR and FBP in low-concentration protocol, and Mann-Whitney U test was used between low-concentration group with IR and conventional protocol. Non-inferiority test was done for diagnostic acceptability between two protocol arms.

Results: In terms of radiation dose, low-concentration protocol showed significantly lower effective dose (3.44 vs. 5.70 mSv, P < .001). Subjective diagnostic acceptability was improved with IR compared to FBP in low-concentration protocol (3.63 ± 0.52 vs. 4.06 ± 0.45, P < .001). Although diagnostic acceptability was significantly lower in low-concentration protocol with IR compared to conventional protocol (4.06 ± 0.45 vs. 4.50 ± 0.37, P < .001), all subjects showed more than standard diagnostic acceptability (score ≥ 3) and difference was in the predefined non-inferiority margin. SNR, CNR and FOM were significantly higher in low-concentration protocol at all segments of urinary tract (P < .001).

Conclusions: Image quality of CTU with 240 mg I/mL iodine content contrast media, 80 kVp tube voltage and iterative reconstruction algorithm were lower than conventional protocol. However, its diagnostic acceptability was still maintained as standard or above quality. Furthermore, SNR, CNR and FOM were superior to conventional protocol. Considering risk of contrast media-induced nephropathy and radiation, low-concentration contrast media with low tube voltage CTU might be beneficial to reduce total amount of iodine contrast media and radiation exposure.

Keywords: Computed Tomography, Urography, Contrast Media, Radiation Dosage

Student number: 2012-23630

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LIST OF ABBREVIATIONS

BMI = Body-mass index

CIN = Contrast media-induced nephropathy

CNR = Contrast to noise ratio

$CTDI_{vol}$ = Volume CT dose index

CTU = Computed tomography urography

DLP = Dose-length product

FBP = Filtered back projection

FOM = Figure of merit (= CNR^2 / effective dose)

IR = Iterative reconstruction

MIP = Maximum intensity projection

ROI = Region of interest

SNR = Signal to noise ratio

INTRODUCTION

For the imaging evaluation of patients presented with hematuria or acute flank pain, computed tomography urography (CTU) is considered as an image of choice because it has high sensitivity and specificity by excellent contrast and spatial resolution of multiplanar imaging of the urinary system (1-3). However, CTU is consisted of multiple phases of scans and should cover large areas of abdomen and pelvis; therefore it involves high radiation exposure (1, 4). There have been many attempts to reduce the radiation dose of CTU, including low tube voltage protocol (5), reduce scan phase with split bolus technique (6) and low tube current protocol with iterative reconstruction (7).

Reduction of tube voltage can decrease radiation exposure. In contrast, increased noise could undermine image quality. However, one study suggests that image quality of excretory CTU is not significantly different between 100 kVp and 120 kVp (8). A published study suggested that 80 kVp images from dual-energy CT scans were feasible for CTU (9). A few previous studies performed with 80 kVp tube voltage revealed that there was no significant difference in diagnostic acceptability in abdominal CT imaging (10, 11). In addition to reducing radiation dose, their studies used reduced amount of contrast media. Because the tube voltage is closer to the energy level of K-shell of iodine (33.2 keV), the attenuation of iodinated contrast material increased. Therefore, they could maintain degree of enhancement with reduced use of contrast media. Reducing the amount of contrast agent may be potential benefit to the patients' safety with low tube voltage technique. The patient who is candidate to CTU could have more chance to having impaired renal function, using low-concentration contrast media that contains smaller amount of total iodine and lower osmolality could be potential benefit to prevent contrast media-induced nephropathy (CIN).

Lowering the tube voltage can increase image noise and beam-hardening artifact due to reduced X-ray penetration and its energy (12). Recently adopted iterative reconstruction algorithm in replace of conventional filtered back projection can reduce image noise without degrading spatial resolution. Several studies advocate the merit of iterative reconstruction to reduce noise with low tube current not only in abdominal imaging (10, 11) but also in CTU (7).

To our knowledge, there is no study on low tube voltage acquisition in conjunction with low-concentration contrast media in excretory CTU with iterative reconstruction. Therefore, the aim of the present study was to investigate the feasibility and image quality of excretory CTU with low iodine concentration contrast media (240 mg I/mL) and low tube voltage (80 kVp).

MATERIALS AND METHODS

Study Population

Institutional review board approved this prospective study, and a written informed consent was obtained from all of the patients. This study was performed on 66 consecutive patients referred from urology clinic in Seoul National University Hospital from March 2013 to February 2014. The inclusion criteria for the study were: (a) presence of clinical indication to perform CTU with the age ranged between 20-70 years; (b) normal renal function (serum creatinine level < 1.4 mg/dL, estimated glomerular filtration rate $\geq$ 37 mL/min/1.73m^2) from blood chemical test which was obtained within 1 month. The exclusion criteria were: (a) absence of previous renal function test result or impaired renal function, (b) history of urinary obstruction, (c) history of urological surgery or procedure which may affect renal excretion, (d) known anatomical variation which may affect image interpretation, (e) contraindication for CT contrast media, (f) proven or possible pregnancy.

Patients were evaluated with chief complaint of gross hematuria (n = 21), microscopic hematuria (n = 18), asymptomatic urinary abnormality (n = 1), follow up for known urinary stone disease (n = 11) and pain/dysuria/lower urinary tract symptoms (n = 13). The patients were randomized into two study arms; low-concentration protocol (240 mg I/mL of contrast media with 80 kVp tube voltage) and conventional protocol (350 mg I/mL of contrast media with 120 kVp tube voltage). Stratified randomization was done to achieve balance of body-mass index (BMI) which may affect image quality, above or below 25 kg/m^2. The randomization result was blinded to patients and researchers at the time of study.

Two patients withdrew their consent before CT examination. One patient in conventional protocol arm underwent excretory phase scan with 100 kVp of tube voltage; finally there were 63 patients in per-protocol study population [32 (18 men; 14 women) in low-concentration arm, 31 (18 men; 13 women) in conventional protocol arm]. Further statistical analysis was performed based on per-protocol population. The mean age ± standard deviation in low-concentration protocol arm and conventional protocol arm were 52.9 ± 11.6 years (range, 24-70) and 57.3 ± 8.3 years (range, 37-70), respectively (P = .147). The BMI were 23.8 ± 2.65 kg/m^2 (range, 18-28.1) and 24.4 ± 3.19 kg/m^2, (range, 19-32.5), respectively (P = .611). There were 9 and 11 patients who had BMI > 25 kg/m^2 in low-concentration protocol and conventional protocol, respectively.

Computed Tomography and Contrast Media Infusion Protocols

All patients were underwent three-phase CTU with precontrast, corticomedullary and excretory phase scans. Images were obtained with 64 channel multi-detector CT scanner (Ingenuity CT; Philips Healthcare, The Netherlands).

Precontrast and corticomedullary phase scans were obtained with 100 kVp of tube voltage as routine protocol in our institution. In case of the patients' BMI

> 25 kg/m^2, 120 kVp of tube voltage was used to increase penetration on corticomedullary phase scan. Other scan parameters are as follows; rotation time, 0.5 second; detector collimation, 64 × 0.625 mm; beam pitch, 0.891; scan field-of-view, 50 cm, cephalocaudal direction from the liver dome to symphysis pubis. The patients were instructed to hold their breath with tidal inspiration during scanning. An 18-gauge intravenous catheter inserted into a right antecubital vein, and 1.5 mL/kg (maximum 110 mL) of ioversol was injected using power injector, followed by 50 mL of normal saline chaser. The contrast injection rate setting was 5 mL/s. In low-concentration protocol arm, 509 mg/mL (240 mg I/mL) of ioversol (Iversense 240, Taejoon pharm, Korea) was used. In conventional protocol arm, 741 mg/mL (350 mg I/mL) of ioversol (Iversense 350, Taejoon pharm, Korea) was used. The volume of contrast media in each arm was constant ratio as 1.5 mL/kg, therefore total iodine amount was reduced in 31.4% in low-concentration protocol arm. Approximately 480 seconds after intravenous administration of contrast media, excretory phase scan was performed. We used low tube voltage to maintain attenuation value caused by decreased total iodine amount in low-concentration protocol. The rationale to reduce tube voltage in low-concentration protocol arm was based on the fact that decreasing the tube voltage from 120 to 80 kVp can reduce the amount of iodine contrast by approximately 40% by published studies (13). Therefore, the tube voltage setting was 80 kVp in low-concentration protocol arm and 120 kVp in conventional protocol arm in excretory phase scan. To compensate reduced penetration of X-ray beam in low tube voltage, tube current was increased in

low-concentration protocol. Combined angular and z-axis automatic tube current modulation were applied. Automatic exposure control (DoseRight, Philips Healthcare) was applied with average tube current of 330 mAs in low-concentration protocol and 120 mAs in conventional protocol.

CT Image Reconstruction

The excretory phase images were reconstructed with section thickness of 5 mm in axial images and 3 mm in coronal and sagittal reconstruction images. In addition, thick slab (3 cm) coronal maximum intensity projection (MIP) images were obtained. Images were reconstructed by using a filtered back projection (FBP) algorithm with sharp convolution kernel (YA) in both study arms. To improve noise from reduced tube voltage in low-concentration protocol, same excretory phase image sets were also reconstructed with hybrid iterative reconstruction (IR) algorithm (iDose^4, Philips Healthcare, The Netherlands) with level of 4. All images were reconstructed with 25 to 40 cm display field-of view depending on the patients’ body habitus. Therefore comparison was done among three groups; low-concentration protocol with FBP, low-concentration protocol with IR and conventional protocol.

Estimation of Radiation Dose

The $CTDI_{vol}$ and DLP were reported in CT scanner console and saved as Digital Imaging and Communications in Medicine (DICOM) file. To convert to effective dose from DLP, age and sex specific conversion factors based on modification of publication 103 of the International Commission on

Radiological Protection (14) were used (0.0132-0.0173, according to sex and tube voltage).

Qualitative Image Analysis

Qualitative and quantitative imaging analyses were performed by using picture archiving and communication system workstations (M-view 5.4, Infinitt Healthcare, Korea).

Two radiologists with 9 and 19 years' experience in genitourinary radiology who were blinded to image protocol were evaluated excretory phase images independently, for sharpness of contour of the urinary tract, homogeneity of urinary tract, image noise, streak artifact and overall diagnostic acceptability. The mean value of two reader was used for further analysis. Two image sets in low-concentration protocol group which were reconstructed with FBP and IR were presented separately; therefore the readers evaluated a total of 95 image sets which were in one of three groups: low-concentration protocol with FBP, low-concentration protocol with IR and conventional protocol. Readers were allowed to change window width and level as desired to evaluate image sets. Sharpness of urinary contour of the urinary tract were graded on a 3-point scale; 3, sharp delineation of the contour; 2, contour sharpness intermediate between scores 1 and 3; 1, blurred delineation of the urinary tract contour. Image noise, defined as image graininess were graded on a 3-point scale; 3, no image noises throughout each structure; 2, minor image noises not affecting the visualization of normal structures; 1, major image noises affecting the visualization of normal structures. Streak artifacts, mainly attributable to beam hardening, were graded on a 3-point scale; 3, no streak artifacts throughout each structure; 2, minor streak artifacts not affecting the visualization of normal structures; 1, major streak artifacts affecting the visualization of normal structures. Finally, overall diagnostic acceptability of the urinary tract was graded on 5-point scale; 1, non-diagnostic image quality; 2, suboptimal or limited image quality; 3, standard (acceptable) image quality; 4, better than standard image quality and 5, excellent image quality. The average value of two raters was used for further statistical analysis.

To evaluate the degree of urinary tract filling and further quantitative measurement, urinary tract was divided into 4 segments into calyx, renal pelvis, upper and lower urinary tract. Upper ureter was defined as ureter segment from ureteropelvic junction to level of iliac crest. Lower ureter was defined from level of iliac crest to ureterovesical junction. The readers assessed urinary tract filling as 3 categories at thick slab MIP images; no contrast filling, partial contrast filling (< 90%) or complete contrast filling (≥ 90%).

Quantitative Image Analysis

For quantitative image analysis, approximately 60-100 mm^2 circular regions of interests (ROIs) were drawn at renal parenchyma, psoas muscles and urinary bladder on the axial images (Figure 1), mean attenuation values and standard deviation of pixel values were recorded. For four urinary tract segments, approx. 2-20 mm^2 circular ROIs were drawn at each segment of urinary tract on axial or coronal images which better visualize urinary tract, mean attenuation values were recorded (Figure 1). All measurements were performed twice and mean value was recorded. For the segment which was rated as no contrast filling by qualitative inspection, the quantitative measurement was not performed. Signal to noise ratio (SNR), contrast to noise ratio (CNR) and figure of merit (FOM) were calculated at both side of urinary tract segments and urinary bladder. SNR were calculated as follows; SNR = mean attenuation value / image noise. Standard deviation in ipsilateral renal parenchyma (for calyx and renal pelvis) or psoas muscle (for ureter or urinary bladder) was used as image noise. CNR of calyx or renal pelvis were calculated as following formula; CNR = (mean attenuation value − mean attenuation of ipsilateral renal parenchyma) / image noise. CNR of ureter or urinary bladder were calculated similarly; CNR = (mean attenuation value − mean attenuation of ipsilateral psoas muscle) / image noise. To compare the CNR independent of the effective dose, FOM quantity was introduced. (15) The FOM was defined as CNR^2 / effective dose.

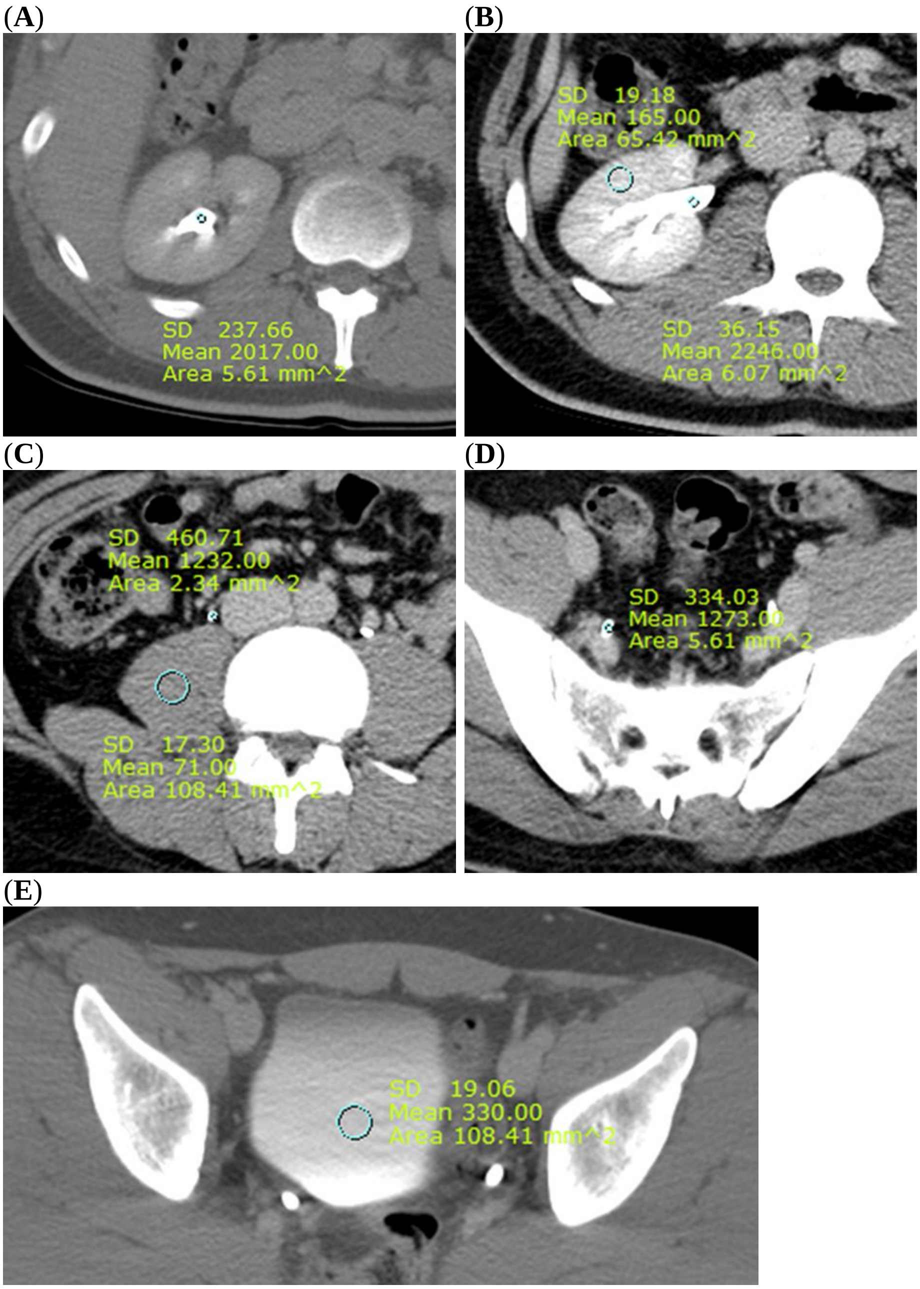


Figure 1. Quantitative measurements of urinary tract.

Quantitative measurement was done with multiple ROIs at (**A**) major calyx, (**B**) renal pelvis and renal parenchyma, (**C**) upper ureter and psoas muscle, (**D**) lower ureter and (**E**) urinary bladder. Both side of urinary tract were measured separately (Figures show only right side measurement).

Statistical Analysis

Pairwise comparison between FBP and IR of low-concentration protocol and independent comparison between low-concentration protocol with IR and conventional protocol were performed for quantitatively rated image scores and qualitatively measured values.

For the comparison of IR and FBP in low-concentration protocol arm, Wilcoxon signed-rank test was performed qualitatively rated image score. Mann-Whitney U test was used to compare radiation dose, quantitatively measured values and qualitatively rated image scores of low-concentration protocol with IR and conventional protocol. Subgroup analysis of diagnostic acceptability was performed according to BMI (cutoff value of 25 kg/m^2) to investigate the effect of patients' physique.

The study sample size was calculated based on non-inferiority study design (16). There have been no published consensus of non-inferiority margin of score diagnostic acceptance in diagnostic imaging, we assumed that diagnostic acceptability $\geq$ 3 (standard image quality) is regarded at least acceptable in clinical practice. The previous study that evaluated diagnostic acceptability of CTU performed on 120 kVp similar to our study reported that pooled mean and standard deviation of diagnostic acceptability score with 5-point scale was 4.13 ± 0.81. If we consider score more than 3 are acceptable to clinical use, the 95% confidence interval of score difference could be calculated as -1.47 to -0.79. Therefore, we defined -0.7 as a non-inferior margin to ensure the diagnostic acceptability is more than score 3 compared to conventional protocol. With 2.5% one-sided type I error and 90% statistical power, at least 54 of total study population is needed with same study and control group size. Considering 20% of dropout rate in prospective study, our study population required 67 subjects. Furthermore, non-inferiority statistical test was done for 5-point diagnostic acceptance score between low-concentration protocol with IR and conventional protocol. To evaluate inter-observer agreement for quantitative assessment, Cohen's weighted kappa value was calculated for diagnostic acceptability.

All statistical tests were performed by using software package (SPSS 21 for Windows, IBM, USA). A *P* value less than .05 regarded as presence of a statistically significant difference.

RESULTS

Radiation Exposure

The $CTDI_{vol}$, DLP and effective dose for excretory phase scan were compared between each study arm. The mean dose estimates and reduction ratio are summarized in Table 1. It showed significant lower radiation dose in low-concentration protocol with 39.6% of dose reduction (*P* values are shown in Table 1).

Table 1. The mean CTDIvol, DLP and effective dose for excretory phase scan

Study arm	Low-concentration protocol	Conventional protocol	P value
BMI ≤ 25			
$CTDI_{vol}$ (mGy)	3.83 ± 0.90	6.38 ± 1.54	< .001
DLP (mGy-cm)	195.8 ± 57.1	315.2 ± 78.2	< .001
Effective Dose (mSv)	2.73 ± 0.65	4.48 ± 0.97	< .001
Dose Reduction*	39.1%		
BMI > 25			
$CTDI_{vol}$ (mGy)	5.58 ± 2.30	9.74 ± 1.66	.001
DLP (mGy-cm)	292.5 ± 114.8	517.9 ± 111.5	.002
Effective Dose (mSv)	3.96 ± 1.65	6.89 ± 1.29	.002
Dose Reduction*	41.5%		
All Subjects			
$CTDI_{vol}$ (mGy)	4.62 ± 1.85	7.62 ± 2.20	< .001
DLP (mGy-cm)	237.5 ± 98.4	388.8 ± 129.4	< .001
Effective Dose (mSv)	3.44 ± 1.40	5.70 ± 1.66	< .001
Dose Reduction*	39.6%		

Note - Unless otherwise specified, data are mean ± standard deviation.

* Dose reduction is calculated on the basis of effective dose

Qualitative Analysis

In 3-point scaled qualitatively rated image scores, sharpness of urinary tract and streak artifact were not significantly different between FBP and IR reconstruction algorithm in low-concentration protocol. However, image noise score was significantly higher in IR, suggesting lower noise with IR (Table 2).

Image noise score and streak artifacts were significantly lower in low-concentration protocol with IR compared to conventional protocol (Table 2). However, sharpness of urinary tract contour was not showed significant difference. Two subjects [2/32(6.3%)] showed major streak artifact affecting normal structure in low-concentration protocol arm while no subjects showed major streak artifact in conventional protocol arm.

Table 2. Three-point subjective image quality scores among low-concentration protocol with FBP/IR and conventional protocol

	Low-concentration protocol		Conventional	*P*	*P*
	With FBP	With IR	protocol	value*	value†
BMI ≤ 25					
Sharpness	2.94 ± 0.17	2.94 ± 0.17	3.00 ± 0.00	1.00	.098
Image Noise	2.13 ± 0.27	2.76 ± 0.30	2.70 ± 0.34	<.001	.583
Streak Artifacts	2.13 ± 0.41	2.13 ± 0.41	2.48 ± 0.43	1.00	.006
BMI > 25					
Sharpness	3.00 ± 0.00	3.00 ± 0.00	3.00 ± 0.00	1.00	1.00
Image Noise	2.22 ± 0.36	2.72 ± 0.44	2.64 ± 0.39	.024	.603
Streak Artifacts	2.06 ± 0.17	2.06 ± 0.17	2.50 ± 0.44	1.00	.031
All Subjects					
Sharpness	2.95 ± 0.15	2.95 ± 0.15	3.00 ± 0.00	1.00	.083
Image Noise	2.16 ± 0.30	2.75 ± 0.34	2.68 ± 0.35	<.001	.385
Streak Artifacts	2.11 ± 0.35	2.11 ± 0.35	2.48 ± 0.42	1.00	< .001

Note – Data are mean ± standard deviation.

*Wilcoxon signed-rank test between low-concentration protocol with FBP and IR.

†Mann-Whitney U test between low-concentration protocol with IR and conventional protocol.

In 5-point scaled diagnostic acceptability between FBP and IR in low-concentration group, the IR showed significant improvement of diagnostic acceptability. However, in BMI > 25 group, the difference between FBP and IR was marginally insignificant. One patient [1/32 (3.1%)] in low-concentration protocol arm showed suboptimal diagnostic acceptability with FBP reconstruction, however, all subjects showed at least standard diagnostic acceptability (score ≥ 3) with low-concentration protocol with IR and conventional protocol.

By Mann-Whitney U test between low-concentration protocol with IR and conventional group, the diagnostic acceptability of low-concentration protocol with IR was significantly lower than that of conventional protocol (Table 3). In non-inferiority test, non-inferiority was accepted in all study group and BMI ≤ 25 subgroup (95% confidence interval of score difference are also shown in Table 3). However in BMI > 25 subgroup, the non-inferiority cannot be accepted because its lower margin of difference of score is outside the range of pre-defined non-inferiority margin.

The kappa value of diagnostic acceptability from two readers was 0.436 (fair agreement).

Urinary tract opacification score are presented at Table 4. There is significant difference in both lower ureters; low-concentration protocol arm showed more frequent no contrast filling state.

Table 3. Five-point scaled diagnostic acceptability among low-concentration protocol with FBP/IR and conventional protocol

	Low-concentration protocol		Conventional	95% CI of
	With FBP	With IR	Protocol	difference‡
BMI ≤ 25	3.59 ± 0.53	4.09 ± 0.47	4.48 ± 0.38	-0.64, -0.13
	< .001*	.004†		
BMI > 25	3.72 ± 0.51	4.00 ± 0.43	4.55 ± 0.35	-0.90, -0.19
	.059*	.012†		
All patients	3.63 ± 0.52	4.06 ± 0.45	4.50 ± 0.37	-0.64, -0.23
	< .001*	< .001†		

Note - Unless otherwise specified, data are presented as mean ± standard deviation.

**P*-value calculated from Wilcoxon signed-rank test between low-concentration protocols with FBP versus IR.

†*P*-value calculated from Mann-Whitney U test between low-concentration protocol with IR and conventional protocol.

‡Difference score between low-concentration protocol with IR and conventional protocol. Data are presented as lower and upper margin.

Table 4. Urinary tract opacification

		Low-concentration protocol	Conventional Protocol	*P* value*
Calyx	Right	0 / 5 / 27	0 / 2 / 29	.251
	Left	0 / 3 / 29	0 / 3 / 28	.968
Renal pelvis	Right	0 / 1 / 31	0 / 1 / 30	.982
	Left	0 / 1 / 31	0 / 5 / 26	.081
Upper ureter	Right	3 / 5 / 24	1 / 2 / 28	.111
	Left	3 / 10 / 19	3 / 6 / 22	.798
Lower ureter	Right	2 / 15 / 15	0 / 9 / 22	.040
	Left	8 / 13 / 11	3 / 6 / 22	.005
Urinary Bladder		3 / 12 / 17	0 / 9 / 22	.100

Note − Data are presented as numbers of subjects with no contrast filling / partial contrast filling (<90%) / complete contrast filling (>90%), respectively.

* Mann-Whitney U test

Quantitative Analysis

In comparison between FBP and IR in low-concentration protocol, IR showed significantly lower attenuation value in some of urinary tract segments; however the SNR, CNR and FOM were significantly higher compared to FBP in all urinary tract segments (Table 5). As expected, the standard deviation of pixel values of background tissue (image noise) was significantly lower by using IR compared to FBP in the low-concentration group (Table 6).

In comparison between low-concentration protocol with IR and conventional protocol, low-concentration protocol with IR showed significantly higher the mean attenuation value and the SNR in all segments of urinary tract (Table 5). In addition, attenuation value of background tissue (renal parenchyma and psoas muscle) was also significantly higher in low-concentration protocol with IR. There was no statistically significant difference of the SNR of renal parenchyma and psoas muscle between two study arms ($P > .05$), except in the left kidney. Furthermore the CNR and the FOM of all segments of bilateral urinary tracts were significant higher in low-concentration protocol with IR ($P < .001$). In terms of image noise, the standard deviation of pixel values of background tissue showed significant difference in the bilateral kidney (Table 6); noise was higher in low-concentration protocol with IR compared to conventional protocol. However, the noise of psoas muscle did not demonstrate significant difference between low-concentration protocol with IR and conventional protocol.

The representative images from both protocol arms are presented at Figure 2 and Figure 3.

Table 5. Comparison of quantitatively measured attenuation number, SNR, CNR and FOM of urinary tract

		CT Attenuation Number					Signal-to-noise Ratio				
		Low-concentration protocol		Conventional protocol	*P* value		Low-concentration protocol		Conventional protocol	*P* value	
		With FBP	With IR		*	†	With FBP	With IR		*	†
Calyx	Right	2073 ± 822	2068 ± 824	976 ± 397	.374	< .001	84.5 ± 32.0	113.0 ± 44.0	65.7 ± 30.8	< .001	< .001
	Left	2034 ± 795	2067 ± 814	1049 ± 467	.105	< .001	88.1 ± 36.3	118.4 ± 48.4	70.6 ± 35.8	< .001	< .001
Renal pelvis	Right	2190 ± 746	2190 ± 748	1077 ± 411	.600	< .001	89.5 ± 29.4	119.3 ± 39.0	72.7 ± 33.5	< .001	< .001
	Left	2022 ± 875	1986 ± 869	980 ± 394	.067	< .001	87.6 ± 40.4	113.3 ± 52.1	64.4 ± 32.8	< .001	< .001
Upper ureter	Right	1609 ± 660	1593 ± 698	866 ± 429	.004	< .001	81.7 ± 41.9	112.1 ± 57.8	63.5 ± 33.2	< .001	< .001
	Left	1640 ± 650	1648 ± 637	860 ± 401	.101	< .001	81.7 ± 39.6	114.5 ± 53.5	60.5 ± 33.7	< .001	< .001
Lower ureter	Right	1443 ± 694	1462 ± 699	785 ± 371	< .001	< .001	74.1 ± 41.3	104.2 ± 56.2	58.7 ± 32.9	< .001	< .001
	Left	1489 ± 825	1457 ± 792	837 ± 400	.026	.001	73.3 ± 43.9	100.1 ± 59.0	61.2 ± 35.3	< .001	.005
Urinary bladder		800 ± 521	771 ± 548	374 ± 186	.984	.001	39.5 ± 25.6	52.2 ± 36.5	27.2 ± 14.8	< .001	.004
Renal parenchyma	Right	157 ± 15	156 ± 15	121 ± 19	.003	< .001	6.6 ± 1.3	8.8 ± 1.9	8.0 ± 1.4	< .001	.141
	Left	159 ± 18	159 ± 17	122 ± 14	.258	< .001	6.8 ± 1.3	9.0 ± 1.6	8.2 ± 1.6	< .001	.029
Psoas muscle	Right	72.9 ± 5.5	72.4 ± 5.3	61.8 ± 3.8	< .001	< .001	3.7 ± 0.7	5.1 ± 1.0	4.6 ± 0.9	< .001	.078
	Left	71.5 ± 4.5	71.3 ± 4.5	61.1 ± 3.9	.058	< .001	3.5 ± 0.7	4.9 ± 1.0	4.4 ± 0.9	< .001	.065

Table 5. (Continued)

		Contrast-to-noise Ratio					Figure of Merit				
		Low-concentration protocol		Conventional protocol	*P* value		Low-concentration protocol		Conventional protocol	*P* value	
		With FBP	With IR		*	†	With FBP	With IR		*	†
Calyx	Right	77.9 ± 31.7	104.2 ± 43.6	57.7 ± 30.4	< .001	< .001	2343 ± 2075	4236 ± 3763	795 ± 844	< .001	< .001
	Left	81.3 ± 35.7	109.3 ± 47.7	62.3 ± 35.7	< .001	< .001	2546 ± 1991	4590 ± 3483	958 ± 1495	< .001	< .001
Renal pelvis	Right	82.9 ± 29.1	110.5 ± 38.7	64.7 ± 33.0	< .001	< .001	2490 ± 1955	4453 ± 3547	980 ± 957	< .001	< .001
	Left	80.8 ± 39.9	104.2 ± 51.6	56.2 ± 32.7	< .001	< .001	2531 ± 1968	4205 ± 3268	809 ± 1207	< .001	< .001
Upper ureter	Right	78 ± 41.6	107.1 ± 57.4	58.9 ± 32.9	< .001	< .001	2470 ± 2618	4619 ± 4569	849 ± 1032	< .001	< .001
	Left	78.2 ± 39.2	109.6 ± 53.0	56.1 ± 33.5	< .001	< .001	2357 ± 2333	4579 ± 4359	853 ± 1086	< .001	< .001
Lower ureter	Right	70.4 ± 40.9	99.1 ± 55.7	54.1 ± 32.5	< .001	< .001	2056 ± 2396	3990 ± 4331	798 ± 1261	< .001	< .001
	Left	69.8 ± 43.7	95.2 ± 58.7	56.8 ± 35.0	< .001	.004	2185 ± 2807	3996 ± 5291	902 ± 1400	< .001	< .001
Urinary bladder		35.9 ± 25.4	47.2 ± 36.5	22.7 ± 14.6	< .001	.005	593 ± 800	1129 ± 1596	128 ± 226	< .001	< .001

Note - Unless otherwise specified, data are presented as mean ± standard deviation.

*P-value calculated from Wilcoxon signed-rank test for pairwise comparison between low-concentration protocols with FBP versus IR.

†P-value calculated from Mann-Whitney U test between low-concentration protocol with IR and conventional protocol.

Table 6. Comparison of quantitatively measured noise (standard deviation of pixel values)

		Low-concentration protocol		Conventional protocol	P value	
		FBP	IR		*	†
Renal parenchyma	Right	24.7 ± 5.5	18.6 ± 4.9	15.5 ± 3.2	< .001	0.004
	Left	24.0 ± 4.6	18.1 ± 3.6	15.3 ± 3.3	< .001	0.006
Psoas muscle	Right	20.7 ± 4.3	14.8 ± 2.9	14.1 ± 3.0	< .001	0.254
	Left	21.3 ± 4.4	15.2 ± 3.0	14.5 ± 3.2	< .001	0.302
Root mean square noise		21.0 ± 4.2	24 ± 4.6	14.3 ± 2.9	< .001	0.243

Note - Unless otherwise specified, data are presented as mean ± standard deviation.

*P-value calculated from Wilcoxon signed-rank test for pairwise comparison between low-concentration protocols with FBP versus IR.

†P-value calculated from Mann-Whitney U test between low-concentration protocol with IR and conventional protocol.

(**A**) (**B**)

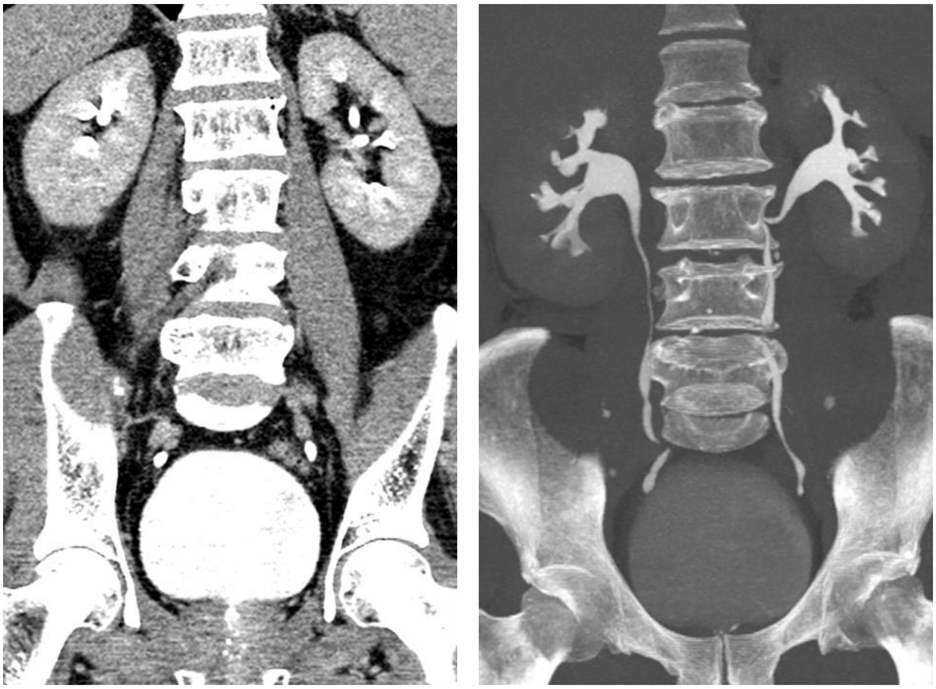


Figure 2. Representative images of low-concentration protocol.

A 64-year-old male with urethral pain.

(**A**) Coronal MPR image of excretory phase CT urography. There was a few papillary calcifications in right kidney and simple cysts in both kidneys. (Not shown on this image) Patient was status post holmium laser enucleation of the prostate.

(**B**) MIP image of the urinary tract. There were tiny high attenuating materials at the bladder neck portion. Right lower ureter was partially filled with contrast media. The bladder stone was confirmed by cystoscopy.

(**A**) (**B**)

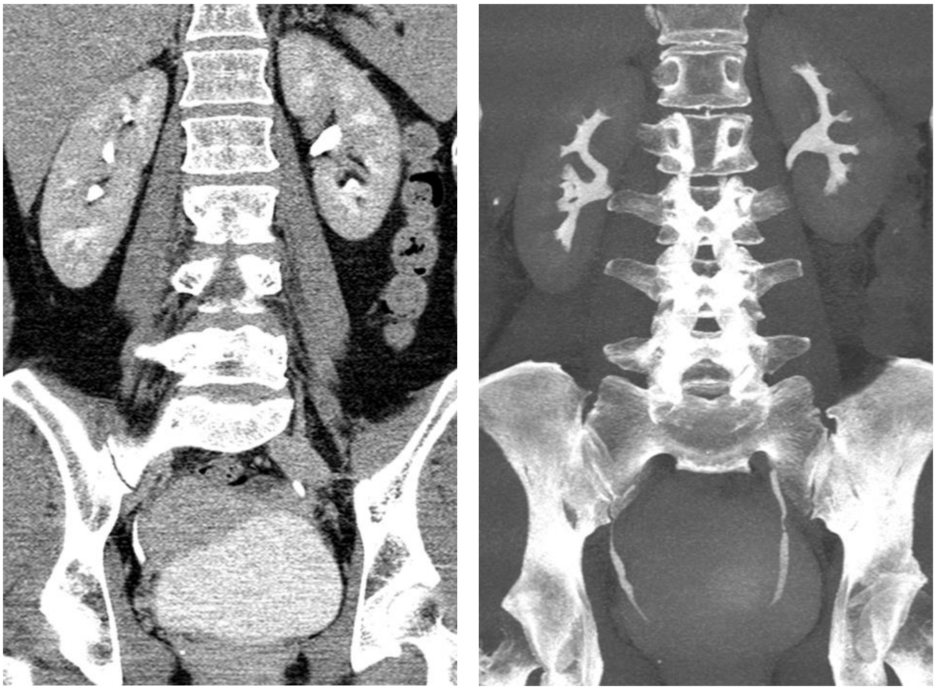


Figure 3. Representative images of conventional protocol. A 48-year-old female with hematuria.

(**A**) Coronal MPR image of excretory phase CT urography

(**B**) MIP image of the urinary tract. There was no focal lesion in the urinary tract.

DISCUSSION

The purpose of our study was to evaluate the feasibility and image quality of low-concentration contrast media (240 mg I/mL) with low tube voltage (80 kVp) to reduce iodine load and radiation dose. By the results, the low-concentration protocol showed higher the attenuation value, the CNR and the FOM in urinary tracts. There are two benefits in our strategy: reduced use of total iodine load might be beneficial for the patients at the risk for CIN. Although it is unclear that reduced amount use of contrast media could reduce the risk of CIN, large dose of iodine contrast media and high osmolality agents have been believed to be a risk factor for contrast media induced nephropathy (17). Our study did not directly investigate the renal protective effect of reduced use of iodinated contrast media, there was no subject who suffered from CIN in our study. Another benefit is reduction of radiation exposure. Increasing concern of risk of medical radiation exposure, low tube voltage scan can decrease radiation exposure because radiation dose is exponentially related to peak tube voltage (18). The effective dose reduction was 39.6% in our study.

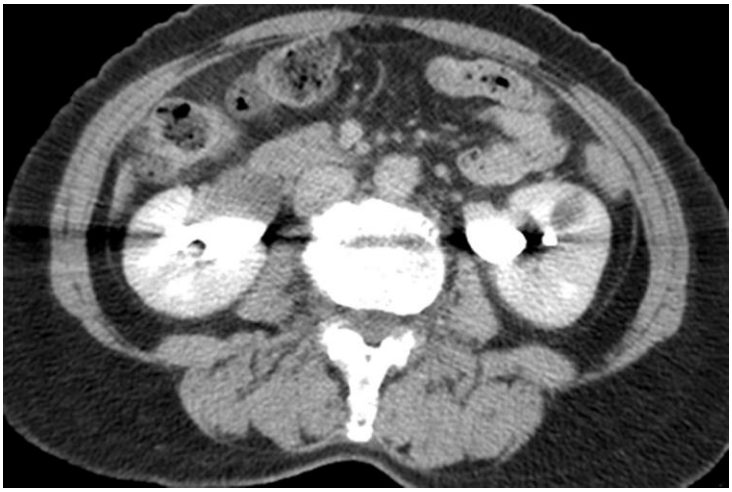
The major evaluation process of excretory CTU is to find filling defects in the urinary tract filled with contrast media caused by urothelial carcinoma, stricture or stones (1). Because of intrinsic high CNR between urinary tract lumen filled with iodine contrast media and background soft tissue, CTU has similar property of CT angiography. There are several published studies for CT angiography with 80 kVp protocol including renal angiography that proved similar or better diagnostic acceptance (19-21). We believe that same rationale could be applied to excretory CTU and our results also support the benefit of low-tube voltage technique.

A drawback of low tube voltage technique is increased image noise (12). However, iterative reconstruction algorithm can significantly decrease the image noise without deterioration of spatial resolution even in low dose CT scans (7, 10). In our study, the subjective image noise, SNR, CNR and FOM of urinary tract were significantly higher in low-concentration protocol with IR compared to FBP reconstruction; while sharpness of urinary tract showed no significant difference. By quantitatively measured noise value (standard deviation of pixel values) also showed no significant difference between low-concentration protocol with IR and conventional protocol in psoas muscle. However in kidney parenchyma, low-concentration protocol with IR showed higher standard deviation of pixel values. It can be explained by increased streak artifact by highly concentrated iodine contrast media in the renal pelvis.

Interestingly, the mean attenuation value of urinary tract in our study was approximately two-fold higher in the low-concentration group. If urinary excretion of contrast media is proportional to concentration of administrated iodine contrast media, the attenuation number of two groups should be similar because we reduced the concentration of contrast media in relation to reduction of tube voltage to result similar attenuation value. Possible explanation is that osmotic diuresis might influence of urine concentration of iodine contrast media. Because osmolality of contrast media was lower in low-concentration group, the effect of osmotic diuresis would be weaker. It is consistent with that low osmolar contrast medium produces higher concentrated urine compared to high osmolar contrast medium (22). In addition, it also could be explained the reason why non-visualized lower urinary tract were more frequently observed in low-concentration group. Furthermore, highly concentrated urine at the renal pelvis make major streak artifact. To overcome these drawbacks, strategies to facilitate sufficient urinary tract distension could be a solution. Several strategies to improve urinary tract distension in CTU were introduced such as furosemide injection, oral hydration or saline infusion (23, 24). After those maneuvers, more water might be excreted to urinary tract to make more diluted urine. Those strategies require further study in conjunction with low-concentration contrast media and low tube voltage for more visualization of dilated ureters and similar attenuation value of conventional protocol.

In our study, there were 2 patients with significant streak artifact that affect major anatomical structure (Figure 4). It was caused by collection of highly concentrated iodine within in the pelvocalyceal system with some degree of ureteropelvic junction obstruction. The major streak artifacts affected the renal parenchyma and disturbed the interpretation of focal lesion. It can be more frequently seen with low osmolality contrast media and the presence of major streak artifact may affect the diagnostic performance (25). That artifact cannot be overcome by IR by our results. In case of urinary tract obstruction or congenital anomaly, the concentrated iodine contrast media at dilated proximal urinary tract could make major streak artifact with low-voltage technique.

(**A**)



(**B**)

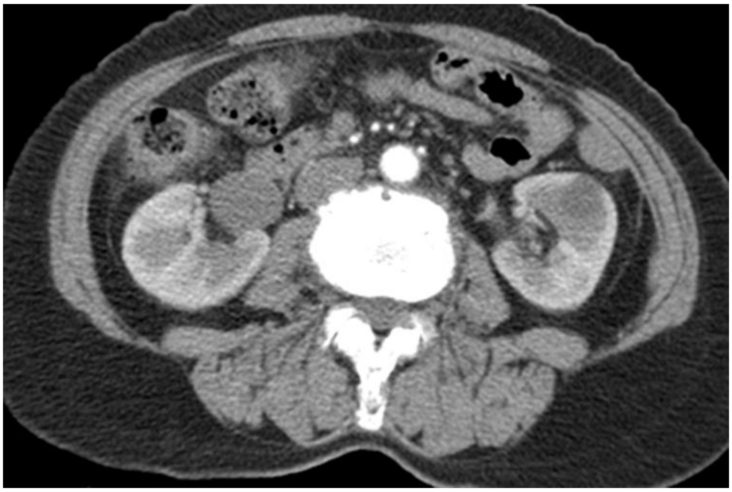


Figure 4. A case of major streak artifact A 61 year-old female patient in low-concentration protocol arm (**A**) Major streak artifact obscures both renal parenchyma. (**B**) A simple cortical cyst is visible in left kidney lower pole on corticomedullary phase image. The patient had calyceal stone in right kidney lower pole (image not shown).

Possible solution is review image with reference of normal-dose corticomedullary phase images (26) However, it is not in the scope of this study, we did not evaluate the combined use of normal dose corticomedullary phase and low-voltage excretory phase image.

Reduced tube voltage can decrease amount use of contrast media; however there is no consensus of concentration of contrast media required for low voltage technique in CTU. For corticomedullary phase of kidney CT, the experimental study revealed that 300 mg I/mL is considered to be the most appropriate concentration (27). However, by our results showed much higher attenuation and SNR in low-concentration protocol, 240 mg I/mL or less could be appropriate for 80 kVp imaging.

The diagnostic acceptability was maintained at least standard diagnostic by non-inferiority test. However in high BMI group, non-inferiority cannot be claimed. The increased body habitus could decrease photon flux and thus increased image noise. By our results, further considerations should be applied for the patients with large body habitus to use 80 kVp tube voltage protocol. Further study should guarantee the stratified use of low tube voltage technique by the patients' habitus.

There are several limitations in our study. First, relatively large non-inferiority margin of diagnostic acceptability was set to demonstrate the image quality more than standard image quality, rather true non-inferiority. The superiority test that compares the mean diagnostic acceptability between low-concentration protocol with IR and conventional protocol demonstrated that significant difference of score, although 95% confidence interval of score difference was above the non-inferiority margin. Our intention of non-inferiority margin was to prove that diagnostic acceptability is at least standard diagnostic (score 3). Furthermore, out study is initial feasibility study, which should not be performed for large population because of ethical issue. Small study population is hard to prove the non-inferiority with strict non-inferiority margin (16).

Second, our study only evaluated image quality, but did not evaluate diagnostic outcomes such as a sensitivity or specificity for lesion detection or clinical outcome. Therefore, to prove non-inferiority of two image protocols should be performed in the larger population with evaluation of diagnostic or clinical outcomes.

Third, we did not evaluate the corticomedullary phase image with reduced concentration of contrast media. Reduced total amount of iodine in the arteries and kidneys possibly decrease attenuation and CNR in corticomedullary phase scans with same scan parameters. A published study performed on 80 kVp tube voltage with moderate-concentration contrast media showed better CNR and diagnostic acceptability for CT renal angiography (19). Because corticomedullary phase are similar to arterial phase, the use of low voltage technique at corticomedullary phase with IR could be a potential solution; however further study should guarantee that strategy.

Finally, because of ethical issue of radiation exposure, the comparison of image quality was not possible for the same patient in our study. However, this shortcoming could be overcome by our randomized prospective study design.

In conclusion, image quality of CTU with 240 mg I/mL iodine content contrast media, 80 kVp tube voltage and iterative reconstruction algorithm were lower than conventional protocol. However, its diagnostic acceptability was still maintained as standard or above quality. Furthermore, SNR, CNR and FOM were superior to conventional protocol. Considering risk of CIN and radiation, low-concentration contrast media with low tube voltage CTU might be beneficial to reduce total amount of iodine contrast media and radiation exposure.

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국문 초록

서론: 본 연구에서는 전산화 단층촬영 요로 조영술에서 요오드 사용량 및 방사선 노출을 줄이기 위해 저농도 요오드 조영제와 저 관전압을 이용한 영상 기법의 가능성을 알아보고, 얻어진 영상의 질을 기존의 영상 방법과 비교 평가하고자 한다.

방법: 본 연구는 전향적 설계로 전산화 단층촬영 요로조영술을 시행할 총 63 명의 환자를 모집하였다. 환자는 조영제 (아이오버솔; ioversol) 주입 후 480 초 후에 시행하는 배출기 영상의 프로토콜에 대하여 무작위 배정을 통해 저농도 조영제군 (240 mg I/mL, *n* = 32)과 기존 조영제군 (350 mg I/mL, *n* = 31) 으로 배정하였다. 기존 조영제군에서는 관전압을 120 kVp 를 사용하였으며, 저농도 조영제군에서는 감쇄를 증가시키기 위해 관전압을 80 kVp 로 낮춰 촬영하였다. 저농도 조영제군에서는 영상 잡음을 줄이기 위한 반복 재구성법 및 기존의 필터 역투사법을 이용한 영상을 모두 얻어서 비교하였다. 두 명의 영상의학과 전문의가 3 점 척도의 요로의 선예도, 영상 잡음, 인공물 및 5 점 척도의 진단의 적합도를 평가하였고, 정량적 분석으로 평균 감쇄값, 신호 대 잡음비 (SNR), 대조도 대 잡음비 (CNR), 및 성능 지수 (FOM)을 계산하였다. 통계적 방법으로 Wilcoxon signed-rank test 를 이용하여 저농도 조영제군에서 반복 재구성법과 필터 역투사법간에 비교를 수행하였고, Mann-Whitney U 검정을 통해 반복 재구성법을 적용한 저농도 조영제군의 영상과 기존 조영제군

의 영상을 비교하였다. 진단적 적합도에 대하여 비열등성 검정을 수행하였다.

결과: 방사선 노출값을 비교하였을 때 저농도 조영제군에서 유의하게 유효선량이 낮았다 (3.44 vs. 5.70 mSv, *P* < .001). 저농도 조영제군에서 반복 재구성법을 적용하였을 때 필터 역투사법을 적용한 영상과 비교하여 주관적 진단적 적합도가 향상되었다 (3.63 ± 0.52 vs. 4.06 ± 0.45, *P* < .001). 기존 조영제군과 비교하여 반복 재구성법을 적용한 저농도 조영제군의 평균 점수가 유의하게 낮게 나타났으나 (4.06 ± 0.45 vs. 4.50 ± 0.37, *P* < .001), 모든 환자에서 표준 진단 적합도 (3점) 이상의 평가를 받았고, 두 군 사이의 평균 점수 차이는 비열등성 한계를 넘지 않았다. 신호 대 잡음비 (SNR), 대조도 대 잡음비 (CNR) 및 성능 지수 (FOM) 모두 저농도 조영제군에서 모든 상부요로 분절에 대하여 유의하게 높은 값을 보였다 (*P* < .001).

결론: 240 mg I/mL 농도의 조영제와 80 kVp 의 관전압 및 반복재구성법을 사용한 전산화 단층촬영 요로조영술의 영상의 질은 기존의 영상 방법보다 차이가 있으나 진단적 적합도는 표준 이상으로 유지되며, 선량을 고려하였을 때 높은 대조도 대 잡음비를 보여주었다. 조영제 유발 신병증과 방사선 피폭의 위험을 고려할 때 저농도 요오드 조영제와 저 관전압을 사용한 전산화 단층촬영 요로조영술은 임상 적용의 타당성이 있을 것으로 생각한다.

주요어 : 전산화 단층 촬영, 요로조영술, 조영제, 방사선 선량

학 번 : 2012-23630